



541.1011CON

**UNITED STATES PATENT AND TRADEMARK OFFICE**

Re: Application of: John N. STANIFORTH, et al.

Serial No.: 10/015,538

Examiner: BENNETT, Rachel M.

Group No.: 1615

Filed: December 13, 2001

For: **A PROCESS FOR PREPARING A DIRECTLY  
COMPRESSIBLE SOLID DOSAGE FORM  
CONTAINING MICROCRYSTALLINE  
CELLULOSE**

**INFORMATION DISCLOSURE STATEMENT**

MAIL STOP: RCE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

November 26, 2003

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97, Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the references cited are enclosed herewith.

It is respectfully requested that the references cited in the accompanying Form PTO-1449 be considered and made of record.

In accordance with the provisions of 37 C.F.R § 1.98 (d), copies of the references cited on pages 1-4 of the attached Form PTO-1449 are not enclosed herewith because these references have been previously submitted to the United States Patent and Trademark Office in parent U.S. Patent Application No. 08/868,745, filed June 4, 1997 (now U.S. Patent No. 6,395,303).

Moreover, pursuant to 37 C.F.R § 1.98 (a) (2) (iii), a copy of the specification, pending claims and drawings for related Published U.S. Patent Application No. 2003/0099702, published May 29, 2003 and Published U.S. Patent Application No. 2003/0131957, published July 17, 2003, which are commonly assigned, are also enclosed. These pending applications are listed on page 5 of Form PTO-1449 as references EA-EB.

It should be noted that WO 9203126, corresponds to U.S. Patent No. 5,322,698. U.S. Patent No. 5,322,698 (reference CH) and WO 9203126 (reference DL) are listed on the Form PTO 1449 and copies of each are attached thereto.

It should also be noted that DE 4303846 corresponds to U.S. Patent No. 5,560,926. Both DE 4303846 (reference DR) and U.S. Patent No. 5,560,926 (reference DE) are listed on the Form PTO 1449 and copies of each are attached thereto.

Applicants also respectfully advise the Examiner of the following related U.S. patents and applications which are commonly assigned:

U.S. Patent Application No. 09/981,319, filed October 16, 2001; U.S. Patent Application No. 09/754,760, filed January 4, 2001 ( now U.S. Patent No. 6,358,533 B2); U.S. Patent Application No. 09/438,646, filed November 12, 1999 (now U.S. Patent No. 6,217,909); U.S. Patent Application No. 08/992,073, filed December 17, 1997 (now U.S. Patent No. 6,103,219); U.S. Patent Application No. 08/724,613, filed September 30, 1996 (now U.S. Patent No. 5,725,884); and U.S. Patent Application No. 08/370,576, January 9, 1995 (now U.S. Patent No.

5,585,115). It is noted that U.S. Patent Nos. 6,358,533; 6,217,909 and 6,103,219 are listed on page 5 of Form PTO 1449 as references EF-EH, respectively and copies of the specification and claims are enclosed herewith. It is further noted that U.S. Patent Nos. 5,725,884 and 5,585,115 are listed on page 4 of Form PTO 1449 as references DA and DC, respectively. As mentioned above, copies of these patents are not enclosed herewith because these patents were previously submitted to the United States Patent and Trademark Office in parent U.S. Patent Application No. 08/868,745, filed June 4, 1997 (now U.S. Patent No. 6,395,303).

U.S. Patent Application No. 09/037,841, filed March 10, 1998 (now U.S. Patent No. 6,106,865); U.S. Patent Application No. 008/660,553, filed June 10, 1996 (now U.S. Patent No. 5,866,166); and U.S. Patent Application No. 08/486,183, filed June 7, 1995 (now U.S. Patent No. 5,725,883). It is noted that U.S. Patent Nos. 6,106,865 and 5,866,166 are listed on page 5 of Form PTO 1449 as references EI and EJ, respectively and copies of the specification and claims are enclosed herewith. It is further noted that U.S. Patent No. 5,725,883 is listed on page 4 of Form PTO 1449 as references DF. As mentioned above, a copy of this patent is not enclosed herewith because this patent was previously submitted to the United States Patent and Trademark Office in parent U.S. Patent Application No. 08/868,745, filed June 4, 1997 (now U.S. Patent No. 6,395,303).

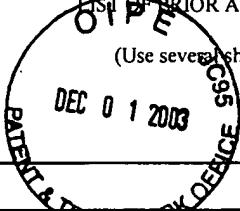
It is respectfully submitted that the pending claims are patentable over all of the references made of record at this time.

This Information Disclosure Statement is being filed together with a Request for Continued Examination (RCE). Accordingly, a check in the amount of \$770.00 is enclosed for the RCE fee. It is believed that no additional fees are due at this time. However, if any additional fees are determined to be due or if any fees have been overpaid, the Commissioner for Patents is hereby authorized to charge said additional fees or credit any overpayment to Deposit Account No. 50-0552.

Respectfully submitted,  
DAVIDSON, DAVIDSON & KAPPEL, LLC

By \_\_\_\_\_  
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Reg. No. 36,561

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FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE								ATTY. DOCKET NO.: 541.1011CON		SERIAL NO.: 10/015538		
 LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)  DEC 01 2003										APPLICANT(S): STANIFORTH, et al.		DEC 05 2003		
										FILING DATE: 12/13/01		GROUP: 1615		
										TECH CENTER 1600/2900				
U.S. PATENT DOCUMENTS														
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE	
	AA	H	1	2	2	9			9/7/93	McGinley, et al.	A23L	654		
	AB	3	0	2	3	1	0	4	2/27/62	Battista, et al.	99	1		
	AC	3	0	6	7	0	3	7	12/4/62	Herald, et al.	99	139		
	AD	3	1	4	1	8	7	5	7/21/64	Battista, et al.	260	212		
	AE	3	5	3	9	3	6	5	11/10/70	Durand, et al.	CO8b	21/30		
	AF	3	5	7	3	0	5	8	3/30/71	Tiemstra, et al.	A23I	1/00		
	AG	4	1	0	9	0	1	8	8/22/78	Thompson	A21D	2/36		
	AH	4	1	4	3	1	6	3	3/6/79	Hutchison, et al.	A23L	1/04		
	AI	4	1	5	6	0	2	1	5/22/79	Richardson	A23D	5/00		
	AJ	4	1	5	9	3	4	5	6/26/79	Takeo, et al.	A61K	47/00		
	AK	4	2	1	9	5	8	0	8/26/80	Torres	A21D	2/18		
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													YES	NO
	AL	WO	90	1	4	0	1	7	11/29/90	PCT	A23L	1/0534	N/A	
	AM	WO	92	1	2	6	3	3	8/6/92	PCT	A01N	25/10	N/A	
	AN	WO	93	1	2	7	6	8	7/8/93	PCT	A61K	9/14	N/A	
	AO	WO	94	0	6	3	0	9	3/31/94	PCT	A23L	1/38	N/A	
	AP	WO	95	2	0	3	2	6	8/3/95	PCT	A23L	1/0534	N/A	
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	AR	Machines Collette High Shear Mixer Granulator Promotional Literature (date unknown)												
	AS													
	AT													
EXAMINER									DATE CONSIDERED					
<small>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</small>														

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE								ATTY. DOCKET NO.: 541.1011CON		SERIAL NO.: 10/01153		
LIST OF PRIOR ART IDENTIFIED BY APPLICANT <i>PATENT &amp; TRADEMARK OFFICE</i> (Use several sheets if necessary)										APPLICANT(S): STANIFORTH, et al.		RECEIVED DEC 05 2003		
										FILING DATE: 12/31/01		GROUP: 1615 TECH CENTER 1600/2900		
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	BB													
	BC	4	6	6	4	9	1	5	5/12/87	Simonian	A61K	31/61		
	BD	4	7	2	1	7	0	9	1/26/88	Seth, et al.	A61K	31/55		
	BE	4	7	4	4	9	8	7	5/17/88	Mehra, et al.	A61K	9/14		
	BF	4	7	4	8	0	2	7	5/31/88	Schou, et al.	A23L	1/035		
	BG	4	8	1	4	1	9	5	3/21/89	Yokoyama, et al.	A23L	1/38		
	BH	4	8	4	9	2	2	7	1/18/89	Cho	A61K	9/16		
	BI													
	BJ	4	9	1	1	9	4	6	3/27/90	Singer, et al.	A23D	3/00		
	BK	4	9	2	3	9	8	1	5/8/90	Weibel, et al.	A61K	47/00		
	BL	4	9	4	6	6	8	5	8/7/90	Edgren, et al.	A61K	9/24		
	BM	4	9	8	0	1	9	3	12/25/90	Tuason, Jr., et al.	A23L	1/522		
	BN	5	0	1	1	7	0	1	4/30/91	Baer, et al.	A23L	0/534		
	BO	5	0	1	9	3	9	7	5/28/91	Wong, et al.	A61K	9/24		
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		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
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	BQ	1	2	6	1	2	6	1	9/2689	Canada	A61K	9/20	N/A	
	BR	0	6	0	9	9	7	6	01/04/94	EP (A1)	CO8B	15/02	N/A	
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	BS													
EXAMINER									DATE CONSIDERED					

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								FILING DATE: 12/31/01	GROUP: 1615	

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U.S. PATENT DOCUMENTS

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	CA	5	0	3	0	4	0	0	7/9/91	Danielsen, et al.	B29B	9/08	
	CB	5	0	7	5	1	1	5	12/24/91	Brine	A61K	9/14	
	CC	5	1	2	6	1	4	5	6/30/92	Evenstad, et al.	A61K	9/20	
	CD	5	1	3	2	1	2	8	7/21/92	Rockland	A23G	3/00	
	CE	5	1	5	8	7	9	8	10/27/92	Fung, et al.	A23D	9/00	
	CF	5	1	9	2	5	6	9	3/9/93	McGinley, et al.	A23L	1/0526	
	CG	5	2	0	9	9	4	2	5/11/93	Bauer, et al.	A23C	1/24	
	CH	5	3	2	2	6	9	8	6/21/94	Kovács, et al.	A61K	9/36	
	CI	5	3	3	8	5	6	2	8/16/94	Humphreys	A23D	9/04	
	CJ	5	3	6	6	7	4	2	11/22/94	Tauson, Jr., et al.	A23L	1/0532	
	CK	5	4	2	9	8	3	0	7/4/95	Janovsky, et al.	A23G	3/00	
	CL	5	4	4	1	7	3	1	8/15/95	Jaxa-Chamiec, et al.	A61K	31/74	
	CM	5	4	4	1	7	5	3	8/15/95	McGinley, et al.	A23L	1/0534	
	CN	5	4	4	7	7	2	9	9/5/95	Belenduik, et al.	A61K	9/16	
	CO												
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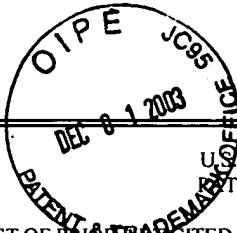
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OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

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## U.S. PATENT DOCUMENTS

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	DA	5	5	8	5	1	1	5	12/17/96	Sherwood, et al.	A61K	9/14	
	DB	5	7	4	1	5	2	4	4/21/98	Staniforth, et al.	A61K	9/14	
	DC	5	7	2	5	8	8	4	3/10/98	Sherwood, et al.	A61K	9/14	
	DD	4	5	3	3	6	7	4	8/6/85	Schmidt, et al.	514	474	
	DE	5	5	6	0	9	2	6	10/1/96	Franz, et al.	424	464	
	DF	5	7	2	5	8	8	3	3/10/98	Staniforth, et al.	424	489	
	DG	5	8	5	8	4	1	2	1/12/99	Staniforth	A61K	9/14	
	DH	5	7	3	3	5	7	8	3/31/98	Hunter, et al.	424	489	
	DI	5	8	5	8	4	0	9	1/12/99	Karetny, et al.	A61K	9/14	
	DJ												
	DK												

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION		
		DL	WO	92	0	3	1	2		PCT	A61K	9/20		YES	NO
	DM	0	5	4	3	5	4	1	5/26/93	EP (A1)	A61K	31/165		N/A	
	DN	1	4	6	4	2	0	0	2/9/77	GB	A61K	31/505		N/A	
	DO	0	3	0	5	0	5	1	3/1/89	EP (A1)	A61K	9/22		N/A	
	DP	1	4	8	0	1	8	8	7/20/77	GB	A61K	9/16		N/A	
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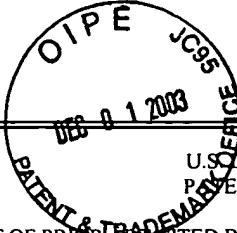
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LIST OF PRIOR ART CITED BY APPLICANT  (Use several sheets if necessary)										APPLICANT(S): STANIFORTH, et al.	RECEIVED DEC 05 2003		
										FILING DATE: 12/13/01	GROUP: 1615 TECH CENTER 1600 2900		
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EB		20	03	00	96	0	0	5	5/22/03	Sherwood, et al.	424	465	
EC		20	03	02	06	9	7	8	11/6/03	Sherwood, et al.	424	728	
ED		20	03	02	03	0	5	0	10/30/03	Sherwood, et al.	424	725	
EE		20	03	00	86	9	8	2	5/8/03	Sherwood, et al.	424	725	
EF		6	3	5	8	5	3	3	3/19/02	Sherwood, et al.	424	494	
EG		6	2	1	7	9	0	9	4/17/01	Sherwood, et al.	424	494	
EH		6	1	0	3	2	1	9	8/15/00	Sherwood, et al.	424	49	
EI		6	1	0	6	8	6	5	8/22/00	Staniforth, et al.	424	489	
EJ		5	8	6	6	1	6	6	2/2/99	Staniforth, et al.	424	489	
EK		6	5	2	1	2	6	1	2/18/03	Sherwood, et al.	424	494	
EL		20	03	01	04	0	7	6	6/5/03	Wilhelm, et al.	424	725	
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		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
													YES
	EM	WO	99	1	5	1	5	5	4/1/99	PCT	A61K	9/20	N/A
	EN	0	6	0	9	9	7	6	8/10/94	EP	C08B	15/02	N/A
	EO	0	6	1	7	1	9	1	9/28/94	EP			Abstract
EXAMINER									DATE CONSIDERED				

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FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE							ATTY. DOCKET NO.: 541.1011CON		SERIAL NO.: 10/011228		
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									FILING DATE: 12/31/01		GROUP: 1615 TECH CENTER 1600/2900		
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FB		6	4	4	7	8	1	5	9/10/02	Menon, et al.	424	737	
FC		6	3	9	5	3	0	3	5/28/02	Staniforth, et al.	424	499	
FD		6	3	9	1	3	3	7	5/21/02	Hunter, et al.	424	474	
FE		6	3	8	3	5	2	6	5/7/02	Andrews, et al.	424	733	
FF		6	2	1	7	9	0	7	4/17/01	Hunter, et al.	424	489	
FG		6	1	9	0	6	9	6	2/20/01	Groenewoud	424	464	
FH		6	1	5	3	2	2	0	11/28/00	Cumming, et al.	424	464	
FI		6	0	3	0	6	4	5	2/29/00	Tritsch, et al.	424	490	
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FQ		4	8	1	0	5	1	6	3/7/89	Kong-Chan	426	548	
FR		4	5	3	6	5	1	1	8/20/85	Fischer, et al.	514	404	
FS		4	5	1	9	9	6	1	5/28/85	Schumacher, et al.	264	4.6	
FT		4	3	9	5	4	9	1	7/26/83	Hohl, et al.	435	262	
FU		2	7	5	6	1	7	7	7/24/56	Cannalonga, et al.	167	81	
EXAMINER									DATE CONSIDERED				

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